K034037

510(K) Summary

JAN 2 8 2004

Disc-O-Tech Medical Technologies Ltd.

SKy Bone Expander System

Company Name

Disc-O-Tech Medical Technologies, Ltd.

3 Hasadnaot St., Herzliya

Israel, 46728

Submitter's Name and Contact Person

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   Disc-O-Tech Medical Technologies, Ltd.

   3 Hasadnaot St. Herzliya, Israel, 46728

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Date Prepared

December 2003

Trade/Proprietary Name

SKy Bone Expander System (SKy System)

Classification

Class II

Predicate Devices

- ✓ B-Twin Bone Expander System (K032358), by Disc-O-Tech Medical Technologies Ltd.
- ✓ KyphX Inflatable Bone Tamp (K981251, K010246, K032212), by Kyphon Inc.

Intended Use

The SKy System is intended for use as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneus.

System Description

The SKy System consists of the following components:

- ✓ Expandable Tube – a tube-like component, mounted on a delivery system. Inserted into the bone in reduced 5-mm diameter configuration and expanded within the bone.
- ✓ Delivery System – used for the insertion, expansion, and retrieval of the expandable tube.
- ✓ Instrumentation Set – a set of accessories to assist in insertion and location of the device.

Substantial Equivalence

The modified SKy System has the following similarities to the B-Twin BE System that previously received 510(k) concurrence:

- ✓ Has the same intended use
- ✓ Has the same operating principles
- ✓ Incorporate the same design principles
- ✓ Incorporate either the same or similar materials
- ✓ Has the same packaging, using the same materials and processes.
- ✓ Has the same, or equivalent, sterilization method, maintaining the same SAL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2004

Disco-O-Tech Medical Technologies Ltd.
C/o Mr. Jonathan S. Kahan, Esq.
Hogan and Hartson L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Re: K034037
Trade/Device Name: SKy Bone Expander System (SKy System)
Regulation Numbers: 21 CFR 888.1100, 21 CFR 888.4540
Regulation Names: Arthroscope, Orthopedic manual surgical instrument
Regulatory Class: II
Product Codes: HRX, HXG
Dated: December 29, 2003
Received: December 29, 2003

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K034037

Device Name: SKy Bone Expander System (SKy System)

Indication for Use:

The SKy System is intended for use as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneus.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K034037